

John E. Flaherty
Ravin R. Patel
MCCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, NJ 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

Attorneys for Plaintiffs

Of Counsel:
Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt
Jacob F. Siegel
PATTERSON BELKNAP
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel.: (212) 336-2000

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P., and)	
JANSSEN SCIENCES IRELAND)	
UNLIMITED COMPANY,)	
)	
Plaintiffs,)	
)	Civil Action No.
v.)	
)	
AMNEAL PHARMACEUTICALS, LLC,)	
AMNEAL PHARMACEUTICALS)	
COMPANY GMBH, AMNEAL)	
PHARMACEUTICALS OF NEW YORK,)	
LLC, AMNEAL PHARMACEUTICALS)	
PVT. LTD. and RAKS PHARMA PVT.)	
LTD.)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (together, "Janssen" or "Plaintiffs") for their Complaint against Defendants Amneal Pharmaceuticals, LLC ("Amneal LLC"), Amneal Pharmaceuticals Company GmbH ("Amneal GmbH"), Amneal Pharmaceuticals of New York, LLC ("Amneal NY"), Amneal Pharmaceuticals

Pvt Ltd. ("Amneal Pvt. Ltd.") and Raks Pharma Pvt. Ltd. ("Raks") (collectively, "Defendants" or "Amneal") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Defendants of U.S. Patent No. 8,518,987 (the "987 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and for a declaratory judgment of infringement of U.S. Patent Nos. 7,126,015 (the "015 Patent") and 7,595,408 (the "'408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Defendants' filing of Abbreviated New Drug Application No. 212493 (the "ANDA"), supported by Drug Master File No. 030803 (the "DMF"), seeking approval to sell generic versions of Janssen's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 600 mg and 800 mg tablets (the "ANDA Products") prior to the expiration of the '987 Patent, the '015 Patent, and the '408 Patent (together, the "patents-in-suit").

THE PARTIES

3. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

4. Plaintiff Janssen Sciences Ireland Unlimited Company is an Irish corporation having its principal place of business at Barnahely, Ringaskiddy, County Cork, Ireland.

5. On information and belief, Amneal LLC is a Delaware limited liability company with a principal place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807. On information and belief, Amneal LLC is in the business of, among other things,

manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market.

6. On information and belief, Amneal GmbH is a company organized and existing under the laws of Switzerland, with a principal place of business at Turmstrasse 30, 6312 Steinhäusen, Switzerland. On information and belief, Amneal GmbH is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Amneal GmbH is a wholly owned subsidiary, alter ago, and agent of Amneal LLC. On information and belief, Amneal GmbH is the holder of the ANDA.

7. On information and belief, Amneal NY is a Delaware limited liability company with its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719 and a place of business at 400 Crossing Blvd., 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal NY is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the U.S. market on behalf of its parent Amneal LLC. On information and belief, Amneal NY is a wholly owned subsidiary, alter ago, and agent of Amneal LLC. On information and belief, Amneal NY is the U.S. regulatory agent of Amneal GmbH with respect to the ANDA. On information and belief, Amneal NY is the U.S. regulatory agent of Raks with respect to the DMF.

8. On information and belief, Amneal Pvt. Ltd. is a company organized and existing under the laws of India, with a registered office at 882/1-871, Near Hotel Kankavati, Village Rajoda, Bavla, Ahmedabad - 382220, Gujarat, India. On information and belief, Amneal Pvt. Ltd. is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market for its parent company Amneal LLC. On

information and belief, Amneal Pvt. Ltd. is a wholly owned subsidiary, alter ago, and agent of Amneal LLC. On information and belief, Amneal Pvt. Ltd. will manufacture the ANDA Products.

9. On information and belief, Raks is a company organized and existing under the laws of India, with a registered office 882/1-871, Near Hotel Kankavati, Village Rajoda, Bavla, Ahmedabad - 382220, Gujarat, India. On information and belief, Raks is in the business of, among other things, manufacturing active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the U.S. market for its parent company Amneal LLC. On information and belief, Raks is a wholly owned subsidiary, alter ago, and agent of Amneal LLC. On information and belief, Raks is the holder of the DMF. On information and belief, Raks will manufacture the API for the ANDA Products.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. On information and belief, this Court has personal jurisdiction over Amneal LLC, *inter alia*, because Amneal LLC's principal place of business is located in New Jersey.

12. On information and belief, this Court has personal jurisdiction over Amneal LLC because Amneal LLC has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Amneal LLC is registered to do business in New Jersey. On information and belief, Amneal LLC has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this

judicial district, and selling pharmaceutical products in this judicial district.

13. On information and belief, Amneal LLC derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

14. On information and belief, Amneal LLC has invoked this Court's jurisdiction as Plaintiff in civil actions concerning sales of pharmaceutical products. *See Amneal Pharmaceuticals LLC v. Reckitt Benckiser Pharmaceuticals, Inc. et al.*, Case No. 3:15-cv-08864-MAS-DEA (D.N.J. Dec. 23, 2015); *see also* Answer (Dkt 10) at ¶ 17, *Symed Labs Limited et al. v. Amneal Pharmaceuticals LLC et al.*, 2:18-cv-13628-CCC-MF (D.N.J. Oct. 12, 2018) ("Amneal admits only that it has, in the past, not contested personal jurisdiction and venue of the Court in prior District of New Jersey actions, and has, in the past, asserted claims and counterclaims in this judicial district.").

15. On information and belief, Amneal LLC has also invoked this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigations. *See, e.g.*, Answer and Counterclaims (Dkt. 10), *Senju Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 3:18-cv-05571-BRM-TJB (D.N.J. Aug. 21, 2018); Answer and Counterclaims (Dkt. 7), *Eli Lilly and Company, et al. v. Amneal Pharmaceuticals LLC*, Case No. 2:18-cv-09071-WHW-CLW (D.N.J. July 23, 2018); Answer and Counterclaims (Dkt. 12), *Forest Laboratories, LLC, et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 2:17-cv-11680-ES-SCM (D.N.J. Feb. 15, 2018); Answer and Counterclaims (Dkt. 10), *Sucampo Pharma, LLC, et al. v. Amneal Pharmaceuticals LLC*, Case No. 3:17-cv-02577-PGS-LHG (D.N.J. June 23, 2017); Answer and Counterclaim (Dkt. 11), *AstraZeneca Pharmaceuticals LP, et al. v. Amneal Pharmaceuticals LLC*, Case No. 1:17-cv-01968-RMB-KMW (D.N.J. May 5, 2017); Answer and

Counterclaims (Dkt. 9), *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals LLC*, Case No. 2:17-cv-01440-ES-JAD (July 10, 2017).

16. On information and belief, Amneal LLC has also previously consented to personal jurisdiction in this district in Hatch-Waxman litigations. *See, e.g.*, Answer (Dkt 10) at ¶ 14, *Symed Labs Limited et al. v. Amneal Pharmaceuticals LLC et al.*, Case No. 2:18-cv-13628-CCC-MF (D.N.J. Oct. 12, 2018) ("Amneal will not contest personal jurisdiction as to Defendant Amneal Pharmaceuticals LLC for the purposes of this action only."); Answer (Dkt. 13) at ¶ 11, *Forest Laboratories, LLC, et al. v. Amneal Pharmaceuticals LLC, et al.*, Case No. 2:17-cv-11680-ES-SCM (D.N.J. Jan. 25, 2018) ("Defendants state that, for purpose of this action only, Defendants do not contest this Court's jurisdiction.").

17. On information and belief, Amneal LLC, Amneal NY, Amneal GmbH, Amneal Pvt. Ltd., and Raks operate and act in concert as an integrated, unitary business. On information and belief, Amneal LLC, acting in concert with Amneal NY, Amneal GmbH, Amneal Pvt. Ltd., and Raks, has made and will continue to make substantial and meaningful preparations in this judicial district towards infringement, including the preparation and submission of the ANDA seeking FDA approval to market Amneal's ANDA Products throughout the United States, including in this judicial district, before expiration of the patents-in-suit. On information and belief, among other actions, Amneal LLC signed the Paragraph IV Letter dated November 21, 2018 concerning the ANDA Products (the "Paragraph IV Letter").

18. On information and belief and as stated in the Paragraph IV Letter, Amneal intends to engage in the commercial manufacture, use, or sale of the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of Amneal LLC, Amneal NY, Amneal GmbH, Amneal Pvt. Ltd., and Raks will

therefore cause injury to Janssen in New Jersey.

19. On information and belief, Amneal NY acts as the agent and alter ego of Amneal LLC and Amneal GmbH with respect to the ANDA. On information and belief, one reflection of that is that Amneal's Paragraph IV Letter, which was signed by Amneal LLC, identifies Amneal NY as the party that submitted the ANDA and makes no mention of Amneal GmbH, the entity listed as the ANDA applicant on the face of the ANDA. On information and belief, Amneal NY submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Amneal LLC and Amneal GmbH, including the ANDA seeking FDA approval to market Amneal's ANDA Products before expiration of the patents-in-suit.

20. On information and belief, this Court has personal jurisdiction over Amneal NY because Amneal NY has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Amneal NY has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

21. On information and belief, Amneal NY has a regular and established place of business located in Bridgewater, New Jersey. The Paragraph IV Letter states Amneal NY's address is 400 Crossing Blvd., 3rd Floor, Bridgewater, NJ 08807.

22. On information and belief, Amneal NY, directly and/or through its parent company, Amneal LLC, and/or its affiliates, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

23. On information and belief, Amneal NY derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial

district, directly and/or through its parent company, Amneal LLC, and/or its affiliates.

24. On information and belief, Amneal NY, directly and/or through its parent company, Amneal LLC, and/or its affiliates, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

25. On information and belief, Amneal NY has invoked this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigations. *See, e.g., Answer and Counterclaims (Dkt. 87), BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al., Case No. 2:15-cv-05909-KM-JBC; Answer and Counterclaims (Dkt. 15), Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al., Case No. 1:15-cv-02865-RBK-JS (D.N.J. July 13, 2015); Answer and Counterclaim (Dkt. 9), Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals, LLC, et al., Case No. 13-4915-MAS-DEA (D.N.J. Sept. 24, 2013); Answer and Counterclaims (Dkt. 12), Luitpold Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al., Case No. 3:12-cv-05064-JAP-DEA (Nov. 5, 2012).*

26. On information and belief, Amneal NY has also previously consented to personal jurisdiction in this district in Hatch-Waxman litigations. *See, e.g., Answer (Dkt. 87) at ¶ 164, BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al., Case No. 2:15-cv-05909-KM-JBC ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only."); Answer (Dkt. 15) at ¶ 26, Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al., Case No. 1:15-cv-02865-RBK-JS (D.N.J. July 13, 2015) ("Amneal admits that this Court has personal jurisdiction over Amneal New York solely for the purposes of this action.").*

27. On information and belief, Amneal NY has been and is engaging in

activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the ANDA seeking FDA approval to market the ANDA Products throughout the United States, including in New Jersey, before expiration of the patents-in-suit.

28. On information and belief, Amneal GmbH acts as the agent and alter ego of Amneal LLC. On information and belief, Amneal GmbH has submitted or aided and abetted the submission of regulatory filings for generic pharmaceutical products to the FDA on behalf of Amneal LLC, including the ANDA seeking FDA approval to market Amneal's ANDA Products before expiration of the patents-in-suit.

29. On information and belief, Amneal LLC and Amneal GmbH operate and act in concert as an integrated, unitary business. Amneal's website lists the offices of Amneal GmbH as the "International Headquarters" for Amneal. On information and belief, Amneal LLC and Amneal GmbH acted in concert in preparing and submitting or aiding and abetting the submission of the ANDA seeking FDA approval to market Amneal's ANDA Products before expiration of the patents-in-suit and in the preparation of the Paragraph IV Letter.

30. On information and belief, this Court has personal jurisdiction over Amneal GmbH because Amneal GmbH has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Amneal GmbH has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

31. On information and belief, Amneal GmbH has a regular and established place of business located at the principal place of business of Amneal LLC in Bridgewater, New Jersey, where Amneal GmbH regularly conducts business itself and/or through its parent

company, Amneal LLC.

32. On information and belief, Amneal GmbH, directly and/or through its parent company, Amneal LLC, and/or its affiliates, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

33. On information and belief, Amneal GmbH derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its parent company, Amneal LLC, and/or its affiliates.

34. On information and belief, Amneal GmbH, directly and/or through its parent company, Amneal LLC, and/or its affiliates, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

35. On information and belief, Amneal GmbH is the holder of the ANDA and has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting or aiding and abetting the preparation and submission of the ANDA seeking FDA approval to market the ANDA Products throughout the United States, including in New Jersey, before expiration of the patents-in-suit.

36. On information and belief, Amneal Pvt. Ltd. acts as the agent and alter ego of Amneal LLC. On information and belief, Amneal Pvt. Ltd. has submitted or aided and abetted the submission of regulatory filings for generic pharmaceutical products to the FDA on behalf of Amneal LLC, including the ANDA seeking FDA approval to market Amneal's ANDA Products before expiration of the patents-in-suit.

37. On information and belief, Amneal LLC and Amneal Pvt. Ltd. operate and act in concert as an integrated, unitary business. Amneal states publicly on its website that "[t]he

company's expanding operations in India are an integral part of Amneal's R&D and manufacturing capabilities and expertise."

38. On information and belief, this Court has personal jurisdiction over Amneal Pvt. Ltd. because Amneal Pvt. Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Amneal Pvt. Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

39. On information and belief, Amneal Pvt. Ltd. has a regular and established place of business located at the principal place of business of Amneal LLC in Bridgewater, New Jersey, where Amneal Pvt. Ltd. regularly conducts business itself and/or through its parent company, Amneal LLC.

40. On information and belief, Amneal Pvt. Ltd., directly and/or through its parent company, Amneal LLC, and/or its affiliates, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

41. On information and belief, Amneal Pvt. Ltd. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its parent company, Amneal LLC, and/or its affiliates.

42. On information and belief, Amneal Pvt. Ltd., directly and/or through its parent company, Amneal LLC, and/or its affiliates, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

43. On information and belief, Amneal Pvt. Ltd. has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, acting in concert with Amneal LLC, Amneal GmbH, Amneal NY, and Raks in the preparation and submission of the ANDA seeking FDA approval to market the ANDA Products throughout the United States, including in New Jersey, before expiration of the patents-in-suit. On information and belief, Amneal Pvt. Ltd. will manufacture the ANDA Products.

44. On information and belief, Raks acts as the agent and alter ego of Amneal LLC. On information and belief, Raks has submitted or aided and abetted the submission of regulatory filings for generic pharmaceutical products to the FDA on behalf of Amneal LLC, including the ANDA, and supporting DMF, seeking FDA approval to market Amneal's ANDA Products before expiration of the patents-in-suit.

45. On information and belief, Amneal LLC and Raks operate and act in concert as an integrated, unitary business. Amneal states publicly on its website that "[t]he company's expanding operations in India are an integral part of Amneal's R&D and manufacturing capabilities and expertise."

46. On information and belief, this Court has personal jurisdiction over Raks because Raks has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Raks has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing pharmaceutical products that are sold in this judicial district, and selling pharmaceutical products in this judicial district.

47. On information and belief, Raks has a regular and established place of business located at the principal place of business of Amneal LLC in Bridgewater, New Jersey,

where Raks regularly conducts business itself and/or through its parent company, Amneal LLC.

48. On information and belief, Raks, directly and/or through its parent company, Amneal LLC, and/or its affiliates, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

49. On information and belief, Raks derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its parent company, Amneal LLC, and/or its affiliates.

50. On information and belief, Raks, directly and/or through its parent company, Amneal LLC, and/or its affiliates, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

51. On information and belief, Raks has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the DMF seeking FDA approval to manufacture API for the ANDA Products and acting in concert with Amneal LLC, Amneal GmbH, Amneal Pvt. Ltd., and Amneal NY in the preparation and submission of the ANDA seeking FDA approval to market the ANDA Products throughout the United States, including in New Jersey, before expiration of the patents-in-suit. On information and belief, Raks will manufacture the API for the ANDA Products.

52. This Court's exercise of personal jurisdiction over Defendants is fair and reasonable. Defendants are not unduly burdened by litigating this suit in this judicial district. New Jersey has an interest in providing a forum to resolve Hatch-Waxman litigation, including this case, which involves the sale of products in New Jersey and parties doing business in New Jersey. This Court's exercise of jurisdiction will serve the interests of the parties and the judicial

system in efficient resolution of litigation.

53. In the alternative, as to Amneal GmbH, Amneal Pvt. Ltd., and Raks, this Court's exercise of personal jurisdiction is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, Amneal GmbH is a company organized and existing under the laws of Switzerland, with a principal place of business in Steinhauen, Switzerland. On information and belief, Amneal Pvt. Ltd. is a company organized and existing under the laws of India, with a principal place of business in Bavla, Gujarat, India. On information and belief, Raks is a company organized and existing under the laws of India, with a principal place of business in Bavla, Gujarat, India.

54. Under Rule 4(k)(2), for a claim arising under federal law, jurisdiction in any federal court is proper where a defendant is (1) not subject to jurisdiction in any state, and (2) exercise of jurisdiction is consistent with the United States Constitution and laws.

55. Amneal GmbH has availed itself of the laws of the United States by, among other things, seeking FDA approval for the ANDA Products and other generic pharmaceutical products.

56. Amneal Pvt. Ltd. has availed itself of the laws of the United States by, among other things, acting in concert with Amneal LLC, Amneal NY, and Amneal GmbH in seeking FDA approval for the ANDA Products and other generic pharmaceutical products.

57. Raks has availed itself of the laws of the United States by, among other things, filing the DMF seeking FDA approval to manufacture API for the ANDA Products and other generic pharmaceutical products and acting in concert with Amneal LLC, Amneal NY, and Amneal GmbH in seeking FDA approval for the ANDA Products.

58. Litigating in the District of New Jersey would not burden Amneal GmbH,

Amneal Pvt. Ltd., and Raks unduly. Among other things, on information and belief, Amneal GmbH's, Amneal Pvt. Ltd.'s, and Raks's operations are directed from the corporate office of Amneal LLC in Bridgewater, New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Janssen has a substantial interest in obtaining convenient and effective relief for violations of its property interests. And the states also have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

59. Venue is proper in this district for Amneal LLC pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Amneal LLC has committed and will commit acts of infringement in this judicial district and has a regular and established place of business at its headquarters in Bridgewater, New Jersey, located within this judicial district.

60. Venue is proper in this district for Amneal NY pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Amneal NY has committed and will commit acts of infringement in this judicial district and has a regular and established place of business in Bridgewater, New Jersey, located within this judicial district.

61. Venue is proper in this district for Amneal GmbH pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Amneal GmbH is a company organized and existing under the laws of Switzerland and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

62. Venue is proper in this district for Amneal Pvt. Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Amneal Pvt. Ltd. is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

63. Venue is proper in this district for Raks pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Raks is a company organized and existing under the laws of India

and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

BACKGROUND

64. On August 27, 2013, the U.S. Patent and Trademark Office ("PTO") issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit A.

65. Janssen Sciences Ireland Unlimited Company holds title to the '987 Patent.

66. The '987 Patent expires on February 16, 2024.

67. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

68. Janssen Products, L.P. is the holder of approved New Drug Application No. 21-976 for PREZISTA®.

69. Janssen Products, L.P. sells Janssen's PREZISTA® in the United States.

70. PREZISTA® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

71. The FDA's "Orange Book" also lists patents associated with approved drugs. The '987 is listed in the "Orange Book" in association with PREZISTA®. The claims of the '987 Patent cover PREZISTA®.

72. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit B.

73. Janssen Sciences Ireland Unlimited Company holds title to the '015 Patent.

74. The '015 Patent expires on June 21, 2023.

75. On September 29, 2009, the PTO issued the '408 Patent, entitled "Method for the Preparation of (3R,3aS,6aR) Hexhydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit C.

76. Janssen Sciences Ireland Unlimited Company holds title to the '408 Patent.

77. The '408 Patent expires on May 6, 2025.

78. The '015 Patent and the '408 Patent claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), an essential component of darunavir.

79. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a processes patented by the '015 and '408 Patents prior to their expiration.

80. On information and belief, Defendants' preparations include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

81. On information and belief, Defendants intend to use the processes claimed in the '015 and '408 Patents to prepare the bis-THF component of the ANDA Products.

82. On information and belief, that bis-THF is incorporated into and present in the drug substance (darunavir) in the ANDA Products intact and without material change from the bis-THF made by use of Janssen's patented processes.

83. On information and belief, the bis-THF resulting from Janssen's patented

processes is an essential component of the ANDA Products.

84. Immediately after receiving the Paragraph IV Letter, on November 29, 2018, Janssen contacted Amneal and asked for information documenting the process that has been and will be used to manufacture bis-THF for the ANDA Products so that Janssen could evaluate infringement of the '015 and '408 Patents. Despite repeated requests, Amneal has not provided Janssen with the needed information. In particular, Amneal has not provided Janssen with executed batch records, among other documents, showing the process that has been used and will be used to manufacture bis-THF for the ANDA Products.

85. On December 19, 2018, Amneal provided Janssen with a copy of its DMF. The DMF does not include any information concerning the process used to manufacture bis-THF for the ANDA Product. On December 19, Janssen sent an email to Amneal, noting that "[t]he DMF contains no information whatsoever about how the bis-THF component of darunavir . . . is manufactured" and explaining again that Janssen needs that information to evaluate infringement of '015 Patent and the '408 Patent. Janssen again requested executed batch records for the production of bis-THF and stressed that "it is in both parties interests for Amneal to provide this information without further delay if Amneal contends that a non-infringing route is used for the synthesis of bis-THF." Janssen repeated this request in a follow-up email on December 20.

86. To date, Amneal still has not produced the manufacturing information for the bis-THF component of Amneal's ANDA Products despite repeated requests. Amneal's withholding of needed manufacturing information has impeded Janssen's ability to evaluate infringement of the '015 and '408 Patents.

87. Amneal's failure to produce executed batch records or other corroborating manufacturing information for the bis-THF component of its ANDA Products is consistent with

the conclusion that the processes invented by Janssen and protected by the '015 and '408 Patents will be used to manufacture bis-THF for Amneal's ANDA Products. On information and belief, Amneal has not contested infringement of Janssen's patents and continues to withhold its manufacturing information because the bis-THF component of the ANDA Products is made using the processes claimed in Janssen's '015 and '408 Patents and the importation, use, sale, and/or offer for sale of the ANDA Products would infringe the '015 and '408 Patents.

88. The processes claimed in the '015 and '408 Patents are important for the commercial-scale manufacture of bis-THF. These processes have been infringed by numerous generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '015 and '408 Patents. *See Consent Judgment and Order against Teva Defendants (Dkt. No. 804), Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '015 and '408 Patents); *Consent Judgment and Order against Cipla Defendants (Dkt. No. 9)*, *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the '015 and '408 Patents); *Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075)*, *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the '015 Patent); *Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34)*, *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*, Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018) (judgment as to the '015 and '408 Patents); *Amended Consent Judgment and Order against Hetero Defendants (Dkt. No. 55)*, *Janssen Prods., L.P. et al. v. Hetero Labs, Ltd. et al.*, Case No. 2:13-cv-01444-WHW-CLW (D.N.J. Oct. 9, 2018) (judgment as to the '015 and '408 Patents).

89. On information and belief, Amneal LLC, acting itself or through its

subsidiaries, alter egos, and agents, Amneal NY and Amneal GmbH, submitted the ANDA to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the ANDA Products. Amneal's ANDA has been assigned ANDA No. 212493.

90. On information and belief, Amneal LLC, Amneal NY, Amneal GmbH, Amneal Pvt. Ltd., and Raks collaborated in the research, development, preparation and filing of the ANDA and DMF for the ANDA Products.

91. The Paragraph IV Letter was signed by Amneal LLC and stated that the ANDA was submitted by Amneal NY. On information and belief, Amneal GmbH is the holder of record of the ANDA and Amneal NY is Amneal GmbH's authorized U.S. regulatory agent of record for the ANDA, but both Amneal NY and Amneal GmbH operate as the agents and alter egos of Amneal LLC with respect to the ANDA.

92. On information and belief, Amneal LLC will market and/or distribute the ANDA Products if the ANDA is approved by the FDA.

93. On information and belief, Amneal Pvt. Ltd. will manufacture the ANDA Products if the ANDA is approved by the FDA.

94. On information and belief, Raks will manufacture the API for the ANDA Products if the ANDA is approved by the FDA.

95. On information and belief, Amneal LLC, Amneal NY, Amneal GmbH, Amneal Pvt. Ltd., and Raks participated in, contributed to, aided, abetted and/or induced the submission to the FDA of the ANDA.

96. On information and belief, Defendants have acted in concert in seeking approval of the DMF and ANDA prior to expiration of the patents-in-suit.

97. On or about November 26, 2018 and December 14, 2018, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company respectively received Amneal's Paragraph IV Letter stating that Amneal has submitted the ANDA to the FDA, seeking approval to manufacture, use, and sell Amneal's ANDA Products prior to the expiration of the '987 Patent.

98. Amneal's Paragraph IV Letter stated that Amneal's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '987 Patent are not infringed.

99. Amneal does not dispute that the claims of the '987 Patent are valid.

100. Upon receiving Amneal's Paragraph IV Letter, Janssen promptly and repeatedly requested production of tablet and API samples of the ANDA Products (in addition to the information concerning the manufacturing processes for the ANDA Products and their essential bis-THF component discussed above), in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '987 Patent. Janssen informed Amneal that it was in both parties' interest for Amneal to provide to Janssen with the information necessary, including samples, for Janssen to evaluate infringement of Janssen's patents. Janssen first requested the production of samples on November 29 and repeated this request on at least December 6, December 10, December 14, December 18, December 19, December 20, and December 21. However, despite repeated requests for Amneal to provide the needed samples, Amneal has not produced any samples of tablets or API. Amneal's failure to produce any samples of API or tablets impaired Janssen's ability to evaluate infringement of the '987 Patent.

101. Amneal's failure to produce the requested samples and documents is consistent with the conclusion that it has and will infringe Janssen's 987 Patent. On information

and belief, Amneal continues to withhold samples of its API and tablets due to infringement of the '987 Patent.

102. On information and belief, the ANDA Products infringe one or more claims of the '987 Patent.

103. The '987 Patent has been infringed by other generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '987 Patent. *See* Consent Judgment and Order against Teva Defendants (Dkt. No. 13), *Janssen Prods., L.P. et al. v. Teva Pharm. USA, Inc. et al.*, Case No. 2:13-cv-07576-WHW-CLW (D.N.J. Mar. 26, 2014); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015); Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34), *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*, Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018).

104. On information and belief, Defendants had actual and constructive notice of the '987, '015 and '408 Patents prior to the filing of the ANDA seeking approval of Amneal's ANDA Products, including through judgments in Janssen's favor against other generic manufacturers in this Court.

105. On information and belief, Defendants have made and continue to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import Amneal's ANDA Products prior to the expiration of the '987, '015 and '408 Patents.

106. On information and belief, Defendants' actions include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

107. On information and belief, Defendants continue to seek FDA approval of the ANDA and intend to collaborate in the commercial manufacture, marketing and sale of the ANDA Products (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves the ANDA.

108. Plaintiffs commenced this lawsuit within 45 days of the date they received Amneal's notice of ANDA No. 212493 containing a Paragraph IV certification.

COUNT I

**Infringement of the '987 Patent by Defendants
under 35 U.S.C. § 271(e)(2)(A)**

109. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 108 hereof, as if fully set forth herein.

110. Under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '987 Patent by submitting ANDA No. 212493 with a Paragraph IV certification and seeking FDA approval of ANDA No. 212493 to market the ANDA Products prior to the expiration of the '987 Patent.

111. On November 29, Janssen requested production of tablet and API samples for the ANDA Products, among other information, in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '987 Patent. Janssen repeated this request on at least December 6, December 10, December 14, December 18, December 19, December 20, and December 21. Amneal has not yet produced tablet or API samples. Amneal's delays in producing the samples impaired Janssen's ability to evaluate infringement of the '987 Patent.

112. On information and belief, including Amneal's failure to produce requested samples and information, Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '987 Patent would

infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '987 Patent either literally or under the doctrine of equivalents.

113. Amneal's Paragraph IV Letter does not dispute that the '987 Patent is valid.

114. Defendants had actual and constructive notice of the '987 Patent prior to the filing of ANDA No. 212493 seeking approval of the ANDA Products.

115. Janssen has no adequate remedy at law to redress the infringement by Defendants.

116. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '987 Patent.

COUNT II

Declaratory Judgment of Infringement of the '015 Patent by Defendants under 35 U.S.C. § 271(g)

117. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 116 hereof, as if fully set forth herein.

118. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '015 Patent.

119. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

120. Defendants' actions, including, but not limited to, the filing of ANDA No. 212493 with a Paragraph IV certification and Defendants' systematic attempts to meet the

applicable regulatory requirements for approval of ANDA No. 212493 indicate a refusal to change its course of action.

121. On December 19, 2018, Amneal provided Janssen with a copy of its DMF. The DMF does not include any information concerning the process used to manufacture bis-THF for the ANDA Product. On December 19, Janssen sent an email to Amneal, noting that "[t]he DMF contains no information whatsoever about how the bis-THF component of darunavir . . . is manufactured" and explaining again that Janssen needs that information to evaluate infringement of the '015 Patent. Janssen followed up again on December 20 and December 21. To date, Amneal has not produced the requested information. Amneal also has not contested infringement of the '015 Patent.

122. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '015 Patent, Defendants' importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '015 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '015 Patent under 35 U.S.C. § 271(g).

123. On information and belief, Defendants had actual and constructive notice of the '015 Patent prior to the filing of ANDA No. 212493 seeking approval of the ANDA Products.

124. On information and belief, Defendants' infringement of the '015 Patent is willful.

125. Janssen has no adequate remedy at law to redress infringement by Defendants.

126. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT III

**Declaratory Judgment of Infringement of the '408 Patent
by Defendants under 35 U.S.C. § 271(g)**

127. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 126 hereof, as if fully set forth herein.

128. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '408 Patent.

129. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

130. Defendants' actions, including, but not limited to, the filing of ANDA No. 212493 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 212493, indicate a refusal to change its course of action.

131. On December 19, 2018, Amneal provided Janssen with a copy of its DMF. The DMF does not include any information concerning the process used to manufacture bis-THF for the ANDA Product. On December 19, Janssen sent an email to Amneal, noting that "[t]he DMF contains no information whatsoever about how the bis-THF component of darunavir . . . is manufactured" and explaining again that Janssen needs that information to evaluate infringement of the '408 Patent. Janssen followed up again on December 20 and December 21. To date,

Amneal has not produced the requested information. Amneal also has not contested infringement of the '408 Patent.

132. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '408 Patent, Defendants' importation, use, sale and/or offer for sale of Amneal's ANDA Products prior to the expiration of the '408 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '408 Patent under 35 U.S.C. § 271(g).

133. On information and belief, Defendants had actual and constructive notice of the '408 Patent prior to the filing of ANDA No. 212493 seeking approval of Amneal's ANDA Products.

134. On information and belief, Defendants' infringement of the '408 Patent is willful.

135. Janssen has no adequate remedy at law to redress infringement by Defendants.

136. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(a) a judgment that Defendants have infringed the '987 Patent under 35 U.S.C. § 271(e)(2)(A);

- (b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Amneal's ANDA No. 212493 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '987 Patent, including any additional exclusivity period applicable to that patent;
- (c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 212493 would constitute infringement of the '987 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b) and/or (c);
- (d) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 212493, or any colorable variations thereof, until the day after the expiration of the '987 Patent, including any additional exclusivity period applicable to the '987 Patent, and from otherwise infringing one or more claims of the '987 Patent;
- (e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA No. 212493 would constitute infringement of the '015 and '408 Patents, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(g);
- (f) a declaration that Defendants' infringement of the '015 and '408 Patents is willful;
- (g) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic darunavir tablets

described in in ANDA No. 212493, or any darunavir product that includes a bis-THF component made by any colorable variation of the processes used to make the ANDA Products, until after the expiration of the '015 and '408 Patents, and from otherwise infringing one or more claims of the '015 or '408 Patents;

- (h) a declaration that this case is exceptional;
- (i) an award of Janssen's costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and
- (j) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/ John E. Flaherty

John E. Flaherty
MCCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, New Jersey 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

Of Counsel:
Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt
Jacob F. Siegel
PATTERSON BELKNAP
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel.: (212) 336-2000
Fax: (212) 336-2222

*Attorneys for Plaintiffs Janssen Products, L.P.
and Janssen Sciences Ireland Unlimited
Company*

Dated: December 26, 2018

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. However, the matter in controversy involves the validity and infringement of patents currently or previously asserted in this Court against different generic manufacturers in the following actions presided over by the Honorable William H. Walls:

- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*,
Civil Action No. 10-cv-05954-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Hetero Drugs, Ltd. et al.*,
Civil Action No. 13-cv-01444-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*,
Civil Action No. 13-cv-03891-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Teva Pharmas. USA, Inc. et al.*,
Civil Action No. 13-cv-07576-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*,
Civil Action No. 14-cv-01370-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*,
Civil Action No. 14-cv-05093-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*,
Civil Action No. 15-cv-02549-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*,
Civil Action No. 16-cv-01032-WHW (D.N.J.);
- *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*,
Civil Action No. 17-cv-06872-WHW-CLW (D.N.J.);
- *Janssen Prods., L.P. et al. v. Dr. Reddy's Laboratories, Inc., et al.*,
Civil Action No. 18-cv-09655-WHW-CLW (D.N.J.).

Of Counsel:

Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt

Respectfully submitted,

s/ John E. Flaherty
John E. Flaherty
Ravin R. Patel

Jacob F. Siegel
PATTERSON BELKNAP
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel.: (212) 336-2000
Fax: (212) 336-2222

Dated: December 26, 2018

McCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, New Jersey 07102
Tel: (973) 639-7903
Fax: (973) 297-3971

Attorneys for Plaintiffs